

July 14, 2010

James L. McNees, CHP, Director  
Office of Radiation Control  
State Department of Public Health  
201 Monroe Street  
P.O. Box 303017  
Montgomery, AL 36130-3017

Dear Mr. McNees:

We have reviewed the proposed changes to the Alabama regulations 420-3-26-.01, .02, .03, .07, and .10, received by our office on May 6, 2010. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 19, 20, 30, 31, 32, 33, 35, 61, 150, and the requirements of the eight amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with David Walter on July 13, 2010.

As a result of our review, we have 15 comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the Alabama regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final Alabama regulations. However, we have determined that if your proposed regulations were adopted incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure [SA-200](#).

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other Alabama regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the FSME website: <http://nrc-stp.ornl.gov/rulemaking.html>.

If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator, at (301) 415-2320 ([kathleen.schneider@nrc.gov](mailto:kathleen.schneider@nrc.gov)) or Donna Janda at (610) 337-5371 ([donna.janda@nrc.gov](mailto:donna.janda@nrc.gov)).

Sincerely,

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Terrence Reis, Deputy Director  
Division of Materials Safety and State Agreements  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosures:  
As stated

COMPATIBILITY COMMENTS ON *Alabama* PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	420-3-26-.02(10)(t)	32.72	2007-1 2007-3	B	<p><b>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for medical use under Part 35</b></p> <p>AL does not have equivalent regulations corresponding to 10 CFR 32.72(a)(2)(iv), 32.72(a)(2)(v), 32.72(b)(3), 32.72(b)(4), 32.72(b)(5)(iii), or 32.72(b)(5)(v).</p> <p>AL needs to rewrite 420-3-26-.02(10)(t)1.(ii)(II) and (III) to read “(II) Registered or licensed with the Alabama Board of Pharmacy or another state agency as a drug manufacturer, (III) Licensed as a pharmacy by the Alabama Board of Pharmacy or another State Board of Pharmacy; [insert equivalent text to 10 CFR 32.72(a)(2)(iv)], or [insert equivalent text to 10 CFR 32.72(a)(2)(v)].”</p> <p>AL needs to rewrite 420-3-26-.02(10)(t)1.(iv)(I) to say “...whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution ...”</p> <p>AL needs to insert their equivalent reference to 10 CFR 32.72(a)(2)(iv) in 420-3-26-.02(10)(t)2.</p> <p>AL needs to insert their equivalent reference to 10 CFR 32.72(b)(4) in 420-3-26-.02(10)(t)2.(i).</p> <p>AL needs to rewrite 420-3-26.02(1)(t)2.(ii) to read “... to work as an authorized nuclear pharmacist if: (I) This individual qualifies as an</p>

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
				<p>authorized nuclear pharmacist as defined in 420-3-26-.07(2), (II)This individual meets the requirements in 420-3-26-.07(28)(b) and 420-3-26-.07(30) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or (III) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph [insert equivalent to 10 CFR 32.72(b)(4) once added] of this section.”</p> <p>AL needs to rewrite 420-3-26-.02(10)(t)2.(iii)(III) to read “The permit issued by an Agency, US Nuclear Regulatory Commission, or Agreement State licensee or a Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacists, or (IV) [insert equivalent to 10 CFR 32.72(b)(5)(v)], and (V) A copy of their license or registration to practice nuclear pharmacy by the Alabama Board of Pharmacy or other equivalent State Board of Pharmacy, no later than 30 days after the date that the licensee allows, under paragraphs [insert equivalent for 10 CFR 32.72(b)(2)(i) and (b)(2)(iii)] of this section, the individual to work as an authorized nuclear pharmacist”.</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
2	420-3-26-.02(4)(b)	30.15	2007-2 2007-3	B	<p><b>Certain items containing byproduct material</b></p> <p>AL omits the wording “manufactured prior to November 30, 2007” from 420-3-26-.02(4)(b)1.(viii).</p> <p>AL omits the wording “manufactured prior to December 17, 2007” from 420-3-26-.02(4)(b)2. and (b)3.</p> <p>AL omits equivalent requirements to 10 CFR 30.15(b) from their regulations.</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.15.</p>
3	420-3-26-.02(10)(j)	32.11	2007-2	NRC	<p><b>Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license</b></p> <p>AL needs to remove 420-3-26-.02(10)(j)1. and 2. from its regulations.</p> <p>AL needs to make the above change in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.11.</p>
4	420-3-26-.02(10)(j)3.	32.12	2007-2	NRC	<p><b>Same: Records and material transfer reports</b></p> <p>AL needs to remove 420-3-26-.02(10)(j)3. from its regulations.</p> <p>AL needs to make the above change in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.12.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
5	420-3-26-.02(4)(a)2.	32.13	2007-2	C	<p><b>Same: Prohibition of introduction</b></p> <p>AL needs to remove “pursuant to 420-326-.02(10)(i) or the general license provided in 420-3-26-.02(6) or (7) of this Rule 420-3-26-.02.” and replace it with “except in accordance with a license issued under 10 CFR 32.11.”</p> <p>AL needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 32.13.</p>
6	420-3-26-.03(33)	20.2001	2007-3	C	<p><b>General requirements</b></p> <p>AL omits the reference to their regulation corresponding to 10 CFR 20.2008 from 420-3-26-.03(33)(a)4.</p> <p>AL needs to add the above reference to 420-3-26-.03(33) in order to meet the Compatibility Category C designation assigned to 10 CFR 20.2001.</p>
7	420-3-26-.03(38)	20.2006(e)	2007-3	B	<p><b>Transfer for disposal and manifests</b></p> <p>AL does not have a regulation corresponding to 10 CFR 20.2006(e).</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category B designation assigned to 10 CFR 20.2006(e).</p>
8	N/A	20.2008	2007-3	B	<p><b>Disposal of 11e.(3) and 11e.(4) byproduct material</b></p> <p>AL does not have a regulation corresponding to 10 CFR 20.2008.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					AL needs to add the above regulation in order to meet the Compatibility Category C designation assigned to 10 CFR 20.2001.
9	420-3-26-.02(4)(e)2.	30.18(b)	2007-3	B	<p><b>Exempt quantities</b></p> <p>AL needs to add “before September 25, 1971” between “acquired” and “under” in 420-3-26.02(4)(e)2.</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.18(b).</p>
10	420-3-26-.02(4)(c)	30.20	2007-3	B	<p><b>Gas and aerosol detectors containing byproduct material</b></p> <p>AL needs to replace “or” before “produce” with a “,” and add “or initially transfer for sale or distribution” between “produce” and “gas and aerosol detectors...”. Also, the phrase “life of property” should read “life or property”.</p> <p>AL needs to add the word “initially” before the word transferred in 420-3-26-.02(4)(c)(1) and (2).</p> <p>AL needs to add the following requirement to this section: “before November 30, 2007” in between “or transferred” and “in accordance” in 420-3-26-.02(4)(c)(2).</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.20.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
11	420-3-26-.02(8)(g)	30.32(g)	2007-3	C	<p><b>Application for specific licenses</b></p> <p>AL does not have a regulation corresponding to 10 CFR 30.32(g)(3).</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category C designation assigned to 10 CFR 30.32(g).</p>
12	N/A	30.34(g)	2007-3	H&S	<p><b>Terms and conditions of licenses</b></p> <p>AL does not have a regulation corresponding to 10 CFR 30.34(g).</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category H&amp;S designation assigned to 10 CFR 30.34(g).</p>
13	N/A	32.57	2007-3	B	<p><b>Calibration or reference sources containing Americium-241 or Radium-226: Requirements for license to manufacture or initially transfer</b></p> <p>AL does not have a regulation corresponding to 10 CFR 32.57.</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category B designation assigned to 10 CFR 32.57.</p>



STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
14	N/A	32.102	2007-3	B	<p><b>Schedule-C Prototype tests for Calibration or reference sources containing americium-241</b></p> <p>AL does not have a regulation corresponding to 10 CFR 32.102.</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category B designation assigned to 10 CFR 32.102.</p>
15	420-3-26-.07(52)	35.300 (a)&(b)	2007-3	H&S	<p><b>Use of unsealed byproduct material for which a written directive is required</b></p> <p>AL needs to add "or equivalent NRC or Agreement State requirements" to 420-3-26-.07(52)(a) between "420-3-26-.02" and "or".</p> <p>AL needs to make the above change in order to meet the Compatibility Category H&amp;S designation assigned to 10 CFR 35.300(a) and (b).</p>

## STATE REGULATION STATUS

State: Alabama

Tracking Ticket Number: 10-20

[8 amendment(s) reviewed is identified by a ★

Date: July 14, 2010

at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 <b>(Superceded by 1997-5)</b>	01/10/1994	Final		Alabama has adopted Final Regulations equivalent to RATS ID 1997-5
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 <b>(Superceded by 1997-5)</b>	none	Not Required	Not Required	Alabama has adopted Final Regulations equivalent to RATS ID 1997-5
1991-3	Standards for Protection Against Radiation Part 20 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183;	01/01/1994	Final	No Comments 11/19/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980	10/15/1994	Final	No Comments 04/02/1994	
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 <b>(Superceded by 2002-2)</b>	01/27/1995	Final	No Comments 04/02/1994	Alabama has adopted Final Regulations equivalent to RATS ID 2002-2
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final	No Comments 06/05/1998	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final	No Comments 06/05/1998	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable <sup>1</sup>	Not Applicable	Alabama does not have any licensees subject to these regulations. (See SECY-95-112)
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Final	No Comments 06/05/1998	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	Alabama does not have authority to regulate this material under its Agreement
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final	No Comments 06/05/1998	
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32, 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final	No Comments 06/05/1998	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900	03/13/1998	Final	No Comments 06/05/1998	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final	No Comments 06/05/1998	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superseded by 1997-5)	06/30/1998	Not Required	Not required	Alabama has adopted Final Regulations equivalent to RATS ID 1997-5

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final	No Comments 06/05/1998	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final	No Comments 06/05/1998	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 <b>(Superceded by 2002-2 and 2005-2)</b>	10/20/1998		No Comments 08/29/2000	Alabama has adopted Final Regulations equivalent to RATS IDs 2002-2 and 2005-2
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 <b>(Superceded by 2004-1)</b>	04/01/1999	Final	No Comments 08/29/2000	Alabama has not yet adopted RATS ID 2004-1 in final.
1996-2		02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999	Final	No Comments 08/29/2000	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final	No Comments 08/29/2000	
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final	No Comments 08/29/2000	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final	No Comments 08/29/2000	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 <b>(Superseded by 2004-1)</b>	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078)
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final	No Comments 08/29/2000	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final	No Comments 8/29/00	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final	No Comments 06/05/1998	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773	02/12/2001	Final	No Comments 10/01/2001	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1998-3		07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074)  Alabama has adopted Final Regulations equivalent to RATS IDs 2002-2.

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final	No Comments 08/29/2000	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Final	No Comments 08/29/2000	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final	No Comments 08/29/2000	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Alabama does not have authority to regulate this material under its Agreement
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	Final ML021090092	No Comments 04/25/2002 ML021160517	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML062000076	No Comments 08/10/2006 ML062220014	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML062000076	No Comments 08/10/2006 ML062220014	

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162	02/16/2004	Final ML062000076	No Comments 08/10/2006 ML062220014	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML052940420	No Comments 11/08/2005 ML053120389	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML062000076	No Comments 08/10/2006 ML062220014	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML062000076	No Comments 08/10/2006 ML062220014	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007			
*2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Proposed ML101090107  License Condition ML081960176	No Comments 07/14/2010 ML101580118  Comments 07/28/2008 ML082100083	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35 70 FR 16336; 71 FR 1926	04/29/2008	Final ML062000076	No Comments 08/10/2006 ML062220014	
2005-3	Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128	12/01/2005	License Condition ML052570218	No Comments 09/15/2005 ML052620319	
2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005	03/27/2009	Final ML062610100	No Comments 09/26/2006 ML062700262	Why was this reviewed??

RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
*2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Proposed ML101090107	No Comments 07/14/2010 ML101580118	
*2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Proposed ML101090107  License Condition ML082820556	No Comments 07/14/2010 ML101580118  No Comments 10/21/2008 ML082820596	
*2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML101090107	Comments 07/14/2010 ML101580118	
*2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010	Proposed ML101090107	Comments 07/14/2010 ML101580118	
*2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Proposed ML101090107	Comments 07/14/2010 ML101580118	
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML081090443	No Comments 05/01/2008 ML081220314	
*2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Proposed ML101090107	No Comments 07/14/2010 ML101580118	



RATS ID	NRC Chronology Identification	Date Due for State Adoption		Outgoing Package	Notes
*2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Proposed ML101090107	No Comments 07/14/2010 ML01580118	

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<sup>1</sup> IMPEP Team: verify that Alabama does not have any licensees subject to these regulations during each review.